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APPLICATION NUMBER 09/127,059 FILING DATE 07/31/98 FIRST NAMED APPLICANT LEONARDI ATTY. DOCKET NO. A 648/1D340-US

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HM12/0817

EXAMINER BERNHARDT, E
ART UNIT 1611 PAPER NUMBER

DATE MAILED: 08/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____
 This action is FINAL.
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1 - 20 is/are pending in the application.
Of the above, claim(s) 6 - 18 is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 1 - 5, 19 - 20 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 - 4 - 6
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5,19-20, drawn to compounds and compositions, classified in class 544, subclasses such as 373,377,392,etc.;class 514, subclasses such as 252,254,255.
- II. Claims 6-18, drawn to disorders of the lower urinary tract, classified in class 514, subclasses 252,etc.

The inventions are distinct, each from the other because of the following reasons:

Compounds embraced in I are of differing scope than in II. Thus art which may anticipate or render obvious II would not necessarily do the same for I. Additionally, compounds in I can be used for other purposes as evidenced by the art applied below. Thus they raise different issues of patentability. Note *In re Shetty* 195 USPQ 753.

During a telephone conversation with Mr. Wildman on 1/24/99 a provisional election was made with traverse to prosecute the invention of I, claims 1-5,19-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-18 are withdrawn from

further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claims 1-2,4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. "Optionally substituted" in the claims is unclear as to nature and number of substituent intended.
2. Scope of "aryl" per se is unclear except for phenyl and naphthyl rings since specification appears to also include further fused hetero rings thereon of which only one (i.e. benzodioxane) is specifically described. Note *In re Wiggins* 179 USPQ 421 regarding heterocyclic terminology used in claims.

Claims 1-2,4-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Scope of "optionally substituted", "heteroaryl", "aryl" (other than phenyl and naphthyl) reads on all such functional groups, monocyclic and polycyclic ring systems regardless of complexity of structure, point of attachment to the piperazine residue for which there is no sufficient enabling disclosure by way of working examples or reasonable disclosure of starting material sources. Note *Ex parte Moersch* 104 USPQ 122; *In re Howarth* 210 USPQ 689; *In re Lund* 153 USPQ 625. Compounds made and tested are always 2-alkoxyphenyl as B with Ar groups being phenyl, pyridyl, one mono indolyl, one mono benzodioxinyl. Note *In re Surrey* 151 USPQ 724

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regarding sufficiency of disclosure for a Markush group in cases directed to structure-sensitive arts. Applicants provide no reasonable assurance that representative compounds of the scope claimed will have the requisite activity needed to practice the invention. Note Hagan's compound applied below is a selective 5HT1D antagonist not selective 5-HT1A relied on herein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagan (reference provided by the examiner). Hagan discloses a compound within the instant scope identified as BRL-15572, for use in various screening assays. Hagan published more than a year earlier than applicants' US filing date. Right of priority under 119(e) cannot be granted to applicants who claim foreign priority. Note 119(e) priority is reserved for domestic applicants.

See MPEP 201.04(b) and 706.02(a).

Claims 1,2,4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleeman (US'213). US Kleeman discloses several compounds within the instant scope for use in treating circulation problems. See substituted phenyl piperazines (other than halophenyl and methoxy phenyl derivatives instantly excluded) in column 5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US'078). Ward describes similar compounds to that claimed herein for uses such as treating anxiety. See example 9 which only differs in nature of 2nd ring permitted on the 3-position of the propyl side chain- i.e. imidazolyl vs. instantl pyridyl among other heteroaryls generically embraced. Note that Ward teaches interchangeability of exemplified ring with that claimed herein. See definition of R1 and R2 in column 2. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant pyridyl among others heteroaromatics containing nitrogen, oxygen or sulfur as ring members to be also viable for producing compounds having the uses taught by Ward in view of the equivalency teaching outlined above.

Applicants' IDS od 1/28 and 2/24/99 has been considered except for ref.8 since page 157 is not seen in the IDS packet.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt
EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600 1600